AUTHOR CONTRIBUTIONS

Conception and design: DC, BP, SM
Analysis and interpretation: SM, DC, BP, GW
Data collection: DC, SM
Writing the article: SM, DC, BP, GW
Critical revision of the article: SM, DC, BP, GW, GR
Final approval of the article: SM, DC, BP, GW, GR
Statistical analysis: DC, SM
Obtained funding: Not applicable
Overall responsibility: SM

REFERENCES

1. Perler BA. Carotid endarterectomy: the "gold standard" in the endovascular era. J Am Coll Surg 2002;194:S2-8.
2. Boules TN, Proctor MC, Aref A, Upchurch GR, Stanley JC, Henke PK. Carotid endarterectomy remains the standard of care, even in high-risk surgical patients. Ann Surg 2005;241:356-63.
3. Mullenix PS, Andersen CA, Olsen SB, Tollefson DFJ. Carotid endarterectomy remains the gold standard. Am J Surg 2002;183:580-3.
4. Beneficial effect of carotid endarterectomy in symptomatic patients with high-grade carotid stenosis. North American Symptomatic Carotid Endarterectomy Trial Collaborators. N Engl J Med 1991;325:445-53.
5. Endarterectomy for asymptomatic carotid artery stenosis. Executive Committee for the Asymptomatic Carotid Atherosclerosis Study. JAMA 1995;273:1421-8.
6. Mayberg MR, Wilson SE, Yatsu F, Weiss DG, Messina L, Hershey LA, et al. Carotid endarterectomy and prevention of cerebral ischemia in symptomatic carotid stenosis. JAMA 1991;266:3289-94.
7. Hobson RW, Weiss DG, Fields WS, Goldstone J, Moore WS, Towne JB, et al. Efficacy of carotid endarterectomy for asymptomatic carotid stenosis. N Engl J Med 1993;328:221-7.
8. Horner RD, Oddone EZ, Stechuchak KM, Grambow SC, Gray J, Khuri SF et al. Racial variations in postoperative outcomes of carotid endarterectomy: evidence from the Veterans Affairs National Surgical Quality Improvement Program. Med Care 2002;40:I-35-43.
9. Perler BA, Dardik A, Burleyson GP, Gordon TA, Williams GM. Influence of age and hospital volume on the results of carotid endarterectomy: a statewide analysis of 9918 cases. J Vasc Surg 1998;27:25-31.
10. Dardik A, Bowman HM, Gordon TA, Hsieh G, Perler BA. Impact of race on the outcome of carotid endarterectomy: a population-based analysis of 9,842 recent elective procedures. Ann Surg 2000;232:704-9.
11. Matsen SL, Perler BA, Chang DC. Evidence-based guidelines for carotid endarterectomy operative volume. In preparation, 2006.
12. Matsen SL, Perler BA, Brown PM Jr, Roseborough GS, Williams GM. The distribution of carotid endarterectomy procedures among surgeons and hospitals in New York state: is regionalization of specialized vascular care occurring? J Vasc Surg 2002;36:1146-53.
13. Easton D, Sherman DG. Stroke and mortality rate in carotid endarterectomy: 228 consecutive operations. Stroke 1977;8:565-8.
14. Winslow CM, Solomon DH, Chassin MR, Kosecoff J, Merrick NJ, Brook RH. The appropriateness of carotid endarterectomy. N Engl J Med 1988;318:721-7.
15. Roubin GS, New G, Iyer SS, Vitek JJ, Moussa I, Al-Mubarank N, et al. Immediate and late clinical outcomes of carotid artery stenting in patients with symptomatic and asymptomatic carotid artery stenosis- a 5-year prospective analysis. Circulation 2001;103:532-7.
16. Yadav JS, Roubin GS, Iyer S, Vitek J, King P, Jordan WD, et al. Elective stenting of the extracranial carotid arteries. Circulation 1997;95:376-81.
17. Yadav JS, Wholey MH, Kuntz RE, Fayad P, Katzen BT, Mishkel GJ, et al. Protected carotid-artery stenting versus endarterectomy in high-risk patients. N Engl J Med 2004;351:1493-501.
18. Guidant Corporation. Carotid disease literature review. Available at http://www.guidant.com/reimbursement/carotid/Carotid_Artery_Disease_Review.pdf
19. Reed AB, Gaccione P, Belkin M, Donaldson MC, Mannick JA, Whittemore AD, et al. Perioperative risk factors for carotid endarterectomy: defining the patient at high risk. J Vasc Surg 2003;37:1191-9.
20. Mozes G, Sullivan TM, Torres-Russotto DR, Bower TC, Hoskin TL, Sampaio SM, et al. Carotid endarterectomy in SAPPHIRE-eligible high-risk patients: implications for selecting patients for carotid angioplasty and stenting. J Vasc Surg 2004;39:958-65.
21. Illig KA, Zhang R, Tanski W, Benesch C, Sternbach Y, Green RM. Is the rationale for carotid angioplasty and stenting in patients excluded from ARCHeR justified? J Vasc Surg 2003;37:575-81.
22. Lepore MR, Sternbergh WS, Salartash K, Tonnessen B, Money SR. Influence of NASCET/ACAS trial eligibility on outcome after carotid endarterectomy. J Vasc Surg 2001;34:581-6.
23. Sheikh K, Bullock C, Preston SD. Evaluation of quality improvement interventions for reducing adverse outcomes of carotid endarterectomy. Med Care 2004;42:690-9.
24. Connolly JE. The evolution of extracranial carotid surgery as seen by one surgeon over the past 40 years. Surgeon 2003;1:249-58.
25. Matsen SL, Perler BA, Chang DC. A preliminary clinical scale to predict the risk of in-hospital death after carotid endarterectomy. J Vasc Surg 2005;42:861-8.
26. Halm EA, Chassin MR, Tuhrim S, Hollier LJ, Popp AJ, Ascher E, et al. Revisiting the appropriateness of carotid endarterectomy. Stroke 2003;34:1464-72.
27. Chambers BR, Donnan GA. Carotid endarterectomy for asymptomatic carotid stenosis. The Cochrane Database of Systematic Rev 2005;19:CD001923.
28. Dudley RA, Johansen KL, Brand R, Rennie DJ, Milstein A. Selective referral to high-volume hospitals: estimating potentially avoidable deaths. JAMA 2000;283:1159-66.
29. Riles RS, Imparato AM, Jacobowitz GR, Lamparello PJ, Giangola G, Adelman MA, et al. The cause of perioperative stroke after carotid endarterectomy. J Vasc Surg 1994;19:206-14.
30. Coppi G, Moratto R, Ragazzi G, Nicolosi E, Silingardi R, Benassi Franciosi G, et al. Comparing outcomes of carotid endarterectomy with international benchmarks: audit from an Italian vascular surgery department. Ital Heart J 2005;6:917-21.
31. Rockman CB, Halm EA, Wang JJ, Chassin MR, Tuhrim S, Formisano P, et al. Primary closure of the carotid artery is associated with poorer outcomes during carotid endarterectomy. J Vasc Surg 2005;42:870-7.

Submitted Feb 25, 2006; accepted May 7, 2006.

Additional material for this article may be found online at www.jvascurg.org.

DISCUSSION

Dr Thomas Huber (Gainesville, Fla). The authors have analyzed the outcome after carotid endarterectomy in both Maryland and California over several years using administrative databases. They reported that the overall stroke and mortality rates were less than 1% in both states. The stroke rate decreased over the 10-year time period of the study in Maryland, with race, calendar year, and symptomatology associated with an increased incidence of stroke by logistic regression. Not surprising, the stroke rates in Maryland were inversely related to both hospital and provider specific volumes. I have three questions/requests for the authors.

First, the utility of carotid endarterectomy represents a balance between the risk of stroke associated with the procedure itself and medical management. Although I would like to believe that stroke risk associated with carotid endarterectomy is less than 1% in the two states analyzed, I suspect that the actual rate is significantly higher and that the incidence of stroke is under-reported in the

respective databases. Indeed, the stroke rates for the prospective carotid endarterectomy trials have consistently been higher and a recent Cochrane Review of carotid endarterectomy for asymptomatic stenoses, cited in the draft of the manuscript, reported a 2.9% perioperative stroke or death rate. I would appreciate your insight on the accuracy of the perioperative stroke rate reported in your study.

Second, the incidence of carotid endarterectomies performed for symptomatic lesions was only 15% in both states. This value is significantly lower than traditionally reported and suggests that the methodology for determining the symptomatic status of the carotid lesion is unreliable. Furthermore, the time course of the symptoms relative to the carotid endarterectomy and their laterality are not completely clear. I would appreciate your insight on the reliability of the carotid based symptoms.

Last and perhaps most important, how should these data be interpreted given the expanding role of carotid angioplasty and stent as an acceptable alternative to carotid endarterectomy for extracranial carotid artery occlusive disease?

Dr Bauer Sumpio (New Haven, Conn). I just have two questions. Very interesting presentation, but since you analyzed two states, California and Maryland, I just wondered, as you did the research, was there any difference in the way the data were collected between the two states vis-à-vis payer mix. Since there is a change or perhaps difference in payer mixes that occurred during that 5- to 10-year period, I wonder if that could somehow affect the way that the DRGs are reported and the data is accumulated. My second question has to do with the fact that I believe Dr. Kresowik from Iowa has done some analysis of five different states as well within the Midwest looking at the differences in results among five different Midwest states, and I wonder how your data compares with the data that he has presented.

Dr W. Anthony Lee (Gainesville, Fla). I have a question and kind of a basic comment. You know there are a lot of these databases around and I was wondering why you chose to choose those two states, Maryland simply because the origin of your institution, but why California? Is there something specific about that particular state you wanted to examine? Other studies have come about from New York state and other populous states. When I come across studies like this, which can be kind of broadly described as observational studies, I always wonder what was your initiating or a priori hypothesis if you will—maybe that is a bit of a strong word, but events or ideas or provoking thoughts initiated a study like this rather than just examining a database and seeing what may kind of ultimately shake out, so I was wondering if you could comment on that.

Dr James Elsey (Lawrenceville, Ga). I very much appreciated your paper and it was a fine presentation. I do have one question. The American College is struggling with the accuracy of coding, but at the same time gathering an enormous amount of information derived from coding. I know for a fact that in our hospital, our coding is historically very inaccurate, though not necessarily driven by a particular bias. Much of the data we gather to make decisions is actually quite inaccurate–this becomes evident when we go back and review the charts. Saying that, I wonder how accurate it is to draw scientific and clinical conclusions from retrospective coding. I would like that addressed. Thank you.

Dr Ali AbuRahma (Charleston, WV). I am just standing to emphasize one of the comments by Dr Huber earlier about the indication of surgery. It really worries me to quote a rate of only 15% symptomatic patients in this study. As everybody here knows, carotid stenting is not approved by the government for asymptomatic lesions. The answer of cardiology colleagues and radiology, say, well surgeons are doing it all the time. Guess what? I don't think we do it that way, because every respected article published shows roughly at least 40% to 50% of indication for symptomatic lesions, perhaps even more. To drop it to 15% is really worrisome, so I am really wondering how the data were collected to differentiate between symptomatic and asymptomatic, because that has a great implication on how you practice carotid surgery.

Dr Susanna Matsen. Thank you for those questions. I would like to start with Dr Huber's questions regarding data collection. This also touches on some of the other questions about the potential for under-reporting in the database. We do agree that within any sort of retrospective study such as this based off of databases that there is of course the potential for under-reporting of complications and deaths. We have a few ways that we have addressed this.

For one, we used our own internal hospital database collected by the division of vascular surgery in comparison with the Maryland hospital discharge databases, and these matched with no significant coding inaccuracies identified.

Second, the methodology used in this report was the same as previously used in two papers published by Dr Perler in the *Annals of Surgery* in 2000 and also *JVS* in 1998. We identified the carotids, strokes, and symptomatic patients the same way. Both of those papers quoted significantly higher stroke rates, so it seems clear that surgical outcomes have improved over time.

Third, we have compared the Maryland data set with that from California and found remarkably similar results. If indeed there were gross under-reporting in the Maryland data set, this same gross under-reporting would presumably have been present in the California database. In two states that are 3000 miles apart, the stroke rates were remarkably similar.

Fourth, we did some unpublished analysis of the National Inpatient Sample, which is a different data set that is designed to represent all 50 states. It culls data from 37 states, and we analyzed the stroke rates for all carotids in that data set in 2003 and found a stroke rate of 0.4%.

Lastly, one would think that as medicine becomes more crunched for finances that if anything, the reporting would err on the side of over-reporting, as complications are associated with higher billing.

The second question of Dr Huber regarded symptomatology and whether or not the number of asymptomatic patients was so much larger than the previous studies. I can say that the methodology again was the same, using those six different ICD-9 codes for identifying carotid symptomatology. It was the same as the previous papers published by our group. Second, I think it is fair to say that there is probably an increasing proportion of carotid endarterectomies that are being performed in Maryland on asymptomatic patients. And lastly, it could be that our methodology for collecting this data in looking at those six ICD-9 codes for symptomatology does not identify all symptomatic patients. Perhaps some vascular surgeons are performing carotids on patients they consider to be symptomatic but they do not end up being coded as such. So I think it is difficult to draw too many conclusions except that perhaps there is a decrease in the rate of symptomatic disease patients being operated on in Maryland. Frankly, we believe that the remarkably low rate of perioperative strokes identified in this study and alluded to by the questioners may in fact relate to the very high prevalence of CEAs being performed for asymptomatic disease, where one would anticipate lower rates of perioperative stroke.

The third question by Dr Huber had to do with carotid angioplasty and stenting. We feel that based on the literature, carotid stenting should play a role in the treatment of carotid disease and it is probably most appropriate for high-risk patients. We do feel that carotid endarterectomy remains the gold standard for the majority of patients in contemporary practice at this time.

Regarding difference in the methodology of data collection in the two states, both data sets were taken from parallel or mirroring data sets. The Maryland data was taken from the Health Services Cost Review Commission data set and the California data was taken from the Office of Statewide Health Planning and Development.

Regarding the work of Dr Kresowik, we have not specifically analyzed his data in relation to the present study. In terms of why we used California, it is true that there are many states that have different data sets available for analysis. Previously our group has

studied the New York State data as well as the Maryland data. We chose California for diversity and also because the data set was available to us.

The question addressing the hypothesis is an excellent one. I think it is important to track the rate of these procedures that we are performing in this country as well as outcomes. Since the results of carotid angioplasty are apparently improving with time, we were interested in examining whether such improvement is also occurring with CEA in light of our previously published studies. We also responded to stroke rates that were being quoted in the literature for carotid artery stenting. Of note, the stroke rate published within the SAPPHIRE trial for CEAs was much higher than those published by vascular surgeons in general.

Regarding the question about the ACS coding accuracy, I again would refer to my previous answers about the fact that we had validated this data to the best of our ability with our internal data with the National Inpatient sample and with the California data.

Authors requested to declare conditions of research funding

When sponsors are directly involved in research studies of drugs and devices, the editors will ask authors to clarify the conditions under which the research project was supported by commercial firms, private foundations, or government. Specifically, in the methods section, the authors should describe the roles of the study sponsor(s) and the investigator(s) in (1) study design, (2) conduct of the study, (3) data collection, (4) data analysis, (5) data interpretation, (6) writing of the report, and (7) the decision regarding where and when to submit the report for publication. If the supporting source had no significant involvement in these aspects of the study, the authors should so state.